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10/632,008	07/31/2003	Robert E. Richard	02-263	9358

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
ALAWADI, SARAH	

ART UNIT	PAPER NUMBER
1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,008	RICHARD ET AL.	
	Examiner	Art Unit	
	SARAH AL-AWADI	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/18/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed on 09/18/2008.

The Examiner acknowledges the following:

Claims 1 and 4-23 are presently pending and under examination. Claims 24-27 have been cancelled. Claim 1 has been amended to further include a barrier region disposed over the carrier region. Support for the amendment can be found in paragraphs 0004 to 0007 of the specification. No new matter has been added.

Information Disclosure Statement

No new IDS has been submitted for consideration.

WITHDRAWN REJECTIONS

Rejection Under 35 USC 102(b)

Applicant's amendment to claim 1 which further includes a barrier region renders moot the rejection under 35 USC 102(b) over Crivello et al. United States Patent 4,584,356, and the rejection over Kumar et al. United States Patent 5,057,619. Therefore said rejections are withdrawn.

Rejection under 35 USC 103(a)

The rejection under 35 USC 103(a) as being unpatentable over Crivello et al. in view of Kamath et al. United States Patent 6, 335,029 is hereby **withdrawn** in light of the amendment to claim 1, which further includes a barrier region disposed over the carrier region.

The rejection under 35 USC 103(a) as being unpatentable over Crivello et al. in view of Zukosky et al. United States Patent 4,616,064 is hereby **withdrawn** in light of the amendment to claim 1, which further includes a barrier region disposed over the carrier region.

The rejection under 35 USC 103(a) as being unpatentable over Kumar et al. in view of Zukosky et al. is hereby **withdrawn** in light of the amendment to claim 1, which further includes a barrier region disposed over the carrier region.

NEW REJECTIONS

In light of Applicant's amendments, most notably to claim 1, wherein the device further comprises a barrier region disposed over the carrier region, the following rejections have been newly added:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-9, 17 and 21 are rejected Under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. United States Patent 6,335,029.

Claim 1 recites an implantable or insertable medical device comprising a therapeutic agent and a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient, said polymeric carrier region comprising a silicone copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units, wherein the device further comprises a barrier region disposed over the carrier region.

Kamath et al. teaches an implantable medical device which has a composite layer (carrier layer) of a bioactive agent and a polymer material, and a barrier layer which is positioned over the composite layer which is of adequate thickness to provide controlled release of the bioactive agent. (abstract) Kamath further teaches that the polymeric material for the bioactive agent-

polymer composite layer can include silicones, siloxane polymers, and blends and copolymers thereof. (column 6, lines 29-50).

Claim 4 recites the implantable or insertable medical device of claim 1, wherein said polymeric release region is in the form of a coating layer that covers all or a part of said medical device. Kamath et al. teaches the polymer release region is a coating layer that covers the medical device. (see figure 1, line 5) Furthermore, Kamath teaches that coating selective areas on the coated stent is easily achieved.

Claim 5 recites the implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is selected from a catheter, a guide wire, balloon, a filter, a stent, stent graft, vascular graft, vascular patch, and a shunt. Kamath et al. teaches stent, catheter, balloon, guide wire, cannula or the like.(column 1, lines 24-25)

Claim 6 recites the implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is adapted for implantation or insertion into the coronary vasculature, peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate, or brain. Kamath et al. teaches implantable medical devices which can be inserted into the esophagus, trachea, colon, biliary tract, urinary tract, vascular system or other location within a human or veterinary patient. (column 1, lines 15-23)

Claim 7 recites the implantable or insertable medical device of claim 1, wherein said therapeutic agent is selected from one or more of the group consisting of anti-thrombotic agents, anti-proliferative agents, anti-inflammatory agents, anti-migratory agents, agents affecting extracellular matrix production and organization, anti-neoplastic agents, anti-mitotic agents, anesthetic agents, anti-coagulants, vascular cell growth promoters, vascular cell growth

inhibitors, cholesterol-lowering agents, vasodilating agents, and agents that interfere with endogenous vasoactive mechanisms. Kamath et al. teaches various agents can be used such as anti-inflammatory agents (column 5, line 37) or anti-proliferative agents. (column 6, line 8)

Regarding claim 8, Kamath does not appear to disclose elongation at break data, but in view that the polymers are the same, and an elongation at break of at least 25% is a modest figure, the Examiner takes the position that the Kamath copolymer has the same degree of elongation.

Claim 9 recites the implantable or insertable medical device of claim 1, wherein said non-siloxane units are elevated non-siloxane units which can be selected to be that of vinyl monomers. Kamath et al. teaches copolymers of vinyl monomers can be used. (non-siloxane units) (column 6, line 38) Regarding the elevated Tg, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the non-siloxane units such as vinyl monomers which is instantly claimed, thus is construed as a property of the composition.

Claim 17 recites the implantable or insertable medical device of claim 1, wherein said non-siloxane units are low Tg non-siloxane units corresponding to monomers selected from acrylic monomers, methacrylic monomers, vinyl ether monomers, cyclic ether monomers, ester monomers, unsaturated hydrocarbon monomers, and halogenated unsaturated hydrocarbon monomers. Kamath et al. teaches polyvinyl ethers, and polyvinyl ethers are made up of monomers of vinyl ether. (column 6, line 39) Regarding the low Tg, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered

by the Examiner to be directed toward the non-siloxane units such as vinyl monomers which is instantly claimed, thus is construed as a property of the composition

Claim 21 recites the implantable or insertable medical device of claim 1, wherein said silicone copolymer comprises first and second glass transition temperatures, and wherein said first glass transition temperature is below ambient temperature and wherein said second glass transition temperature is above ambient temperature. Until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the polymer carrier region which is instantly claimed (claim 1), thus is construed as a property of the composition.

Regarding the transition temperatures, in view that the same polymer blocks are disclosed, the glass transition temperatures must also be the same.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to create an implantable medical device with a polymer carrier region comprising a therapeutic agent, and a barrier region comprising a silicone copolymer because Kamath et al. teaches devices which comprise carrier and barrier layers. Kamath et al. suggests that the carrier layer can be made of siloxane polymers comprising siloxane and non-siloxane units. One would have been motivated to do so because Kamath et al. teaches that such devices provide controlled localized delivery of active agents. (column 2, lines 35-43)

Claims 10-16, and 18-19, and 21-23 are rejected Under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. United States Patent 6,335,029 with respect to claim 1 as presented above, further in view of Kumar et al. United States Patent 5,057,619.

Kamath et al. does not expressly teach that the copolymer of the implantable medical device is a block copolymer comprising siloxane units and a block of elevated non-siloxane units. (instant claim 10)

Kumar et al. rectifies this deficiency and exemplifies that polysiloxane-block copolymers are well known. (abstract) Regarding claims 10-14, Kumar et al. teaches that the preferred block copolymers include examples of styrene, methyl methacrylate, methyl acrylate and mixtures thereof (column 9, lines 7-12) which are copolymerized with siloxane. (column 9, lines 40+) Regarding the elevated Tg non-siloxane units, and the recitation of the glass transition temperatures in claims 15 and 16 and 21; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the block copolymer which is instantly claimed. It is an expected property that as the block copolymers are taught, that the glass transition temperatures are the same.

Claim 18 recites the implantable medical device of claim 1, wherein said polymeric release region further comprises a supplemental polymer. The Examiner interprets supplemental polymer in light of the specification (MPEP 2111) to include that of methacrylate polymers and copolymers. Kumar et al. teaches that the preferred block copolymers include examples of styrene, methyl methacrylate, methyl acrylate and mixtures thereof (column 9, lines 7-12) which are copolymerized with siloxane. (column 9, lines 40+) Thus more than one polymer can be present in the release region.

Claim 19 recites the implantable medical device of claim 10, wherein said block copolymer comprises at least two different types of said elevated Tg non-siloxane units. As shown above Kumar et al. teaches various preferred block copolymers which include examples of styrene, methyl methacrylate, and methyl acrylate, and mixtures thereof. (column 9, lines 7-12)

Regarding the limitation of claim 22 which recites the implantable or insertable medical device of claim 10, wherein said block of said siloxane units corresponds to a rubbery phase within said release region at ambient temperatures, and wherein said block of said elevated Tg non-siloxane units corresponds to a hard phase within said release layer at ambient temperatures, as Kumar teaches the preferred block copolymers; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the block copolymer which is instantly claimed.

Claim 23 recites the implantable or insertable medical device of claim 10, wherein said block copolymer is selected from a diblock or triblock copolymer and a graft copolymer. Kumar et al. teaches preferred block copolymers include examples of styrene, methyl methacrylate, methyl acrylate and mixtures thereof. (column 9, lines 7-12) Thus it would have been within the purview of the skilled artisan to create diblocks and triblocks as Kumar suggests block copolymers and mixtures thereof.

It would have been prima facie obvious to the skilled artisan to place block copolymers such as those taught by Kumar on the Kamath medical device because both references teach siloxane and non-siloxane polymers which are placed on medical devices. One would have been motivated to place these block copolymers on the Kamath stent, because Kumar et al. teaches

that a mixtures of polymers similar to Kamath including that of styrenes, and non-siloxane units can be placed on the medical device.

Claim 20 is rejected Under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. United States Patent 6,335,029 with respect to claim 1 as presented above, further in view of Zukosky et al. United States patent Application 4,616,064.

Claim 20 requires that the device be sterilized with sufficient radiation to kill pathogens. Kamath does not disclose sterilization, but in view that the device is a medical device, some sort of sterilization is inherent. Furthermore, Zukosky discloses polymeric compositions, particularly block copolymers comprising polysiloxane and polycarbonate or urethane or amide blocks, and states that they are useful for forming medical tubing which can be radiation sterilized. (column 1, line 30) Accordingly, since Kamath discloses a medical tubing or other devices, and Zukosky discloses that the polysiloxane copolymers similar to that which are used in Kamath may be radiation sterilized, it would have been prima facie obvious to the skilled artisan to radiation sterilize the Kamath medical devices since some sort of sterilization must be performed on medical devices to protect the patient.

All claims still under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/
Examiner, Art Unit 1619

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615